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13th International Conference on

## **CLINICAL GASTROENTEROLOGY, HEPATOLOGY AND ENDOSCOPY**

November 13-14, 2017 | Las Vegas, USA



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#### Infliximab biosimilars (Remsima<sup>TM</sup>) in therapy of IBD patients: Experience form one tertiary IBD center

**Background:** The evidence on efficacy and safety of biosimilars infliximab (IFX) in patients with inflammatory bowel diseases (IBD) is sparse.

**Methods:** One cohort composed of prospectively followed patients who were switched from original to biosimilars IFX. The second cohort included retrospectively assessed anti-TNF $\alpha$  naïve patients who started therapy. Disease activity was assessed using standard clinical indices, endoscopic evaluation, and laboratory parameters. Trough levels (TL) and anti-drug antibodies (ATI) were also measured. Patients were evaluated 56 weeks (W56) after switch and at weeks 14 (W14) and 46 (W46) in the naïve cohort.

**Results:** 74 IBD patients were switched to biosimilars IFX and 119 naïve patients newly initiated therapy with the preparation. Disease activity remained stable in majority of switched patients (remission at W0 vs. W56: 72.2% vs. 77.8%; median difference of both HBI and SCCAI between W0 and W56 was 0). Comparing W0 and W56, no significant difference in CRP and FC was observed. In total, 92% of CD and 83% of UC patients responded to induction therapy (W14) with biosimilars IFX. At W46 the response rate was 86% in CD and 64% in UC. Moreover, half of UC patients experienced mucosal healing at W14 and improvement of perianal disease occurred in 95% of CD at W46. No increase in immunogenicity was found in switched patients and type and frequency of adverse events were comparable to original preparation.

Conclusion: Infliximab CT-P13 is affordable therapy in IBD patients.

#### **Biography**

Milan Lukas is a Professor in ISCARE Lighthouse Clinical Center IBD Clinical and Research Centre ISCARE and 1st Medical Faculty in Charles University, Czech Republic.

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